



american cleaning institute®



April 28, 2021

Theresa Michele, MD  
Director  
Office of Nonprescription Drugs  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

Dear Dr. Michele,

We are writing on behalf of the American Cleaning Institute<sup>1</sup> (ACI) and the Consumer Healthcare Products Association<sup>2</sup> (CHPA) to request that FDA withdraw its *Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*, first issued in March 2020 and last updated on February 10, 2021<sup>3</sup>. It is our understanding that FDA issued this temporary policy in the early days of the COVID-19 pandemic in order to meet the huge increase in market demand for hand sanitizers to help address the COVID-19 public health emergency. FDA specifically states in the temporary policy that: FDA will “continually assess[] the needs and circumstances related to this temporary policy, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate.”

We appreciate the actions of all manufacturers to provide hand sanitizer products to support peak consumer and health system demand during the pandemic. However, we believe it is appropriate to reassess the need for the temporary policy at this time. We note that FDA has had to address ongoing quality and safety issues associated with many of the products manufactured under the temporary policy, likely due to lack of compliance with Current Good Manufacturing Practice requirements (cGMPs). We believe that it is now appropriate to withdraw the guidance and return to manufacturing only by those firms in full compliance with applicable requirements, including cGMPs. There is no longer a need to increase hand sanitizer production in the marketplace to help consumers by increasing the number of manufacturers. As illustrated in the chart below, retail tracking data provided by IRI

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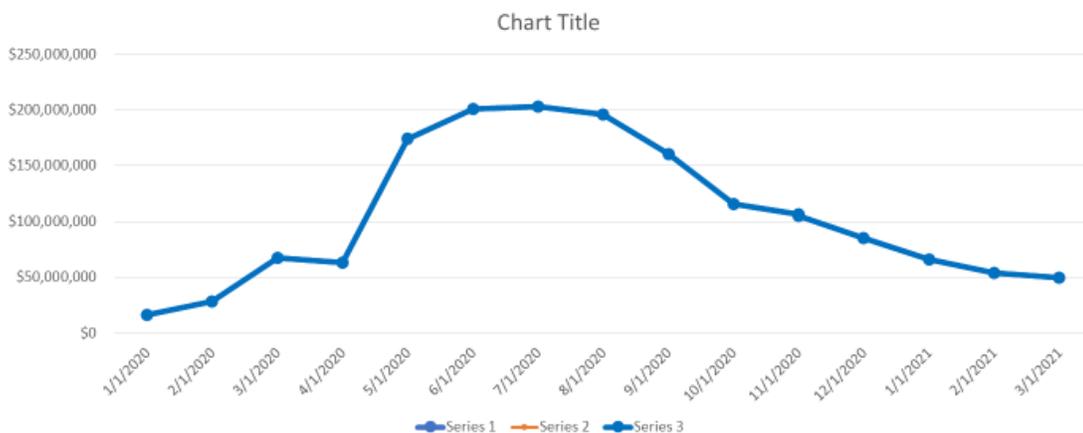
<sup>1</sup> The American Cleaning Institute® (ACI – [www.cleaninginstitute.org](http://www.cleaninginstitute.org)) is the Home of the U.S. Cleaning Products Industry® and its members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI also represents a coalition of topical antiseptic manufacturers that is conducting and sponsoring safety and efficacy studies to meet the gaps identified by FDA in their final OTC topical antiseptic monographs.

<sup>2</sup> The Consumer Healthcare Products Association (CHPA – [www.chpa.org](http://www.chpa.org)), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices.

<sup>3</sup> FDA’s guidance is available here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during>

demonstrates that demand for hand sanitizers at physical retail outlets dramatically increased from \$25-30 million per month before the pandemic to over \$150 million per month from April to September 2020, as Americans sought out these products. At this time, while demand is still at higher than pre-pandemic levels, the demand has dramatically decreased and is more stable, as seen in the figure below. Indeed, current sales for hand sanitizers appear to be lower as of March 1, 2021 than they were on March 1, 2020.

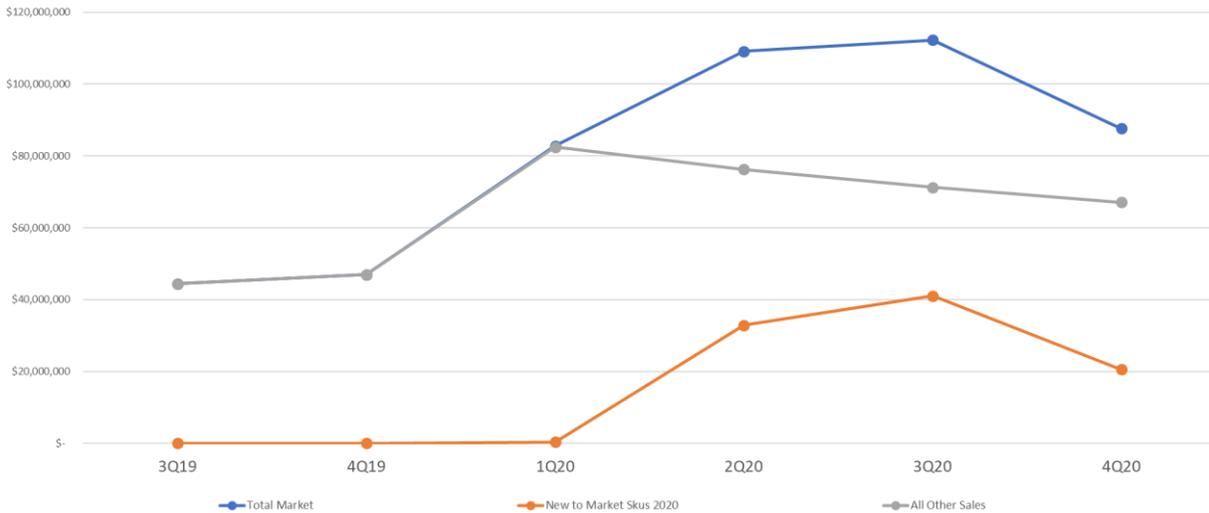
## Hand sanitizer sales by month Total US, MULO Source: IRI, April 16, 2021



Hand sanitizer sales by healthcare distributors provided through Global Healthcare Exchange (GHX) indicate that the third quarter of 2019 through the fourth quarter of 2020 show similar trends to retail sales (figure below). This data was derived from invoice data from the top medical distributors within the Health Industry Distributors Association (HIDA) and is estimated to represent roughly 85% of the U.S. healthcare distributor market. While demand is still at higher than pre-pandemic levels as of Q1 2021, it has dramatically decreased and is on a downward trajectory, as seen in the figure below. The figure also demonstrates that the majority of current hand sanitizer sales in healthcare is accounted for by stock-keeping units (Skus) that were in the market prior to the pandemic, and that there is capacity for these Skus to meet the totality of current demand.

## Hand Sanitizer Sales by Quarter US Healthcare

Source: GHX, April 23, 2021



Although the COVID-19 public health emergency is still ongoing, ACI and CHPA members who are not marketing under the temporary guidance have the capacity to fully supply the marketplace with these products. Our members have strengthened their supply chains for ethanol and other hand sanitizer ingredients and components for the foreseeable future. Similarly, our members have also increased production of cGMP-compliant products to meet the demand for both the consumer and healthcare markets. In addition, the sources identified below document increased ethanol production and indicate that the hand sanitizer market has actually become oversaturated with hand sanitizers manufactured under FDA’s temporary policy:

- USA Today: Panic buying? Not anymore. Suddenly there's a surplus of hand sanitizer<sup>4</sup>
- POET Expands Purified Alcohol Production, Launches Plant-Based Consumer Products<sup>5</sup>
- Viridis Chemical and HELM team on bio-based ethyl acetate and USP ethanol<sup>6</sup>

The foregoing sources indicate that some major ethanol suppliers are committed to a sustained increase in ethanol production. We do not anticipate supply chain issues that would preclude cGMP-compliant manufacturers from meeting current and anticipated demand.

ACI and CHPA recommend that FDA promptly withdraw the temporary policy and require alcohol-based hand sanitizer manufacturing that is not in compliance with cGMPs and other applicable requirements to stop, allowing a reasonable period for manufacturers marketing under the temporary guidance to finish out their pre-existing supply contracts. We further recommend that any product manufactured

<sup>4</sup> <https://www.usatoday.com/story/money/2021/04/08/hand-sanitizer-deals-donations-surplus-panic-buying-pandemic/7120815002/>

<sup>5</sup> <https://www.dtnpf.com/agriculture/web/ag/blogs/ethanol-blog/blog-post/2021/03/31/poet-expands-purified-alcohol-plant>

<sup>6</sup> <https://www.biofuelsdigest.com/bdigest/2021/03/18/viridis-chemical-and-helm-team-on-bio-based-ethyl-acetate-and-usp-ethanol/>

and placed into interstate commerce prior to the withdrawal of the temporary policy be permitted to remain in distribution to allow distributors time to clear current inventory of temporary hand sanitizer.

ACI and CHPA appreciate your leadership on this matter. Please contact me at [jkim@cleaninginstitute.org](mailto:jkim@cleaninginstitute.org) or 202.680.4849 if I can be of further assistance. Thank you.

Best regards,



James Kim, Ph.D.  
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Barbara A. Kochanowski Ph.D.  
SVP, Regulatory & Scientific Affairs



Cc: D. Ashley  
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